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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/930,329 | 08/14/2001 | Thomas H. Turpen | 00801.0103.DVUS02 | 2314 |

22798 7590 05/13/2003

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| EXAMINER |
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LIU, SAMUEL W

| ART UNIT | PAPER NUMBER |
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1653

DATE MAILED: 05/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/930,329

Applicant(s)

TURPEN, THOMAS H.

Examiner

Samuel W Liu

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003 (Paper No. 10).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-35 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 26-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 26-35, drawn to a method of expressing a gene that encodes an antisense RNA in a plant cell, classified in class 536, subclasses 23.1 and 23.72, class 435, subclasses 69.1, 235.1 and 410, class 800, subclasses 278 and 286.
- II. Claims 26-35, drawn to a method of expressing a gene that encodes a ribozyme in a plant cell, classified in class 536, subclasses 23.1 and 23.72, class 435, subclasses 69.1, 235.1 and 410, class 800, subclass 278.
- III. Claims 26-35, drawn to a method of expressing a gene that encodes a regulatory enzyme in a plant cell, classified in class 536, subclasses 23.1, 23.2, 23.5 and 23.72, class 435, subclasses 69.1, 235.1 and 410, class 800, subclasses 278 and 286.
- IV. Claims 26-35, drawn to a method of expressing a gene that encodes a structural protein in a plant cell, classified in class 536, subclasses 23.1, 23.2, 23.5 and 23.72, class 435, subclasses 69.1, 235.1 and 410, class 800, subclasses 278 and 286.
- V. Claims 26-35, drawn to a method of expressing a gene that encodes a therapeutic protein in a plant cell, classified in class 536, subclasses 23.1, 23.2, 23.5 and 23.72, class 435, subclasses 69.1, 235.1 and 410, class 800, subclasses 278 and 286.

The inventions are distinct, each from the other for the following reasons:

Inventions I – V are directed to different and/or distinct methods comprising a polynucleotide that directs biosynthesis of structurally distinct biomolecule, e.g., antisense

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ribonucleotide, ribozyme, and polypeptide. The methods differ with respect to host cell competent to expression of the said gene product (i.e., above stated biomolecules), targets, method steps, and expression outcome including post-transcriptional modification (e.g., self-cleavage of ribozyme) or/and post-translational modification (e.g., prepolypeptide, ro polypeptide or polypeptide *in vivo* posttranslational modification) in the host. Therefore, each method is patentably distinct.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Papers related to this application may be submitted by facsimile transmission to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1) and must conform to the notice published in the Official Gazette, 1096 OG 30 (15 November 1989). The

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telephone number assigned to Art Unit 1804 in the CM1 PTO Fax Center is (703) 308--4242 or 305-3014.

swl

Samuel Wei Liu, Ph.D.

May 8, 2003

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER